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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,758	10/17/2003	Michael T.K. Ling	FLM-5686A	1992
7590	08/08/2006		EXAMINER	
MARK J. BUONAIUTO, ESQ. ASSISTANT GENERAL COUNSEL BAXTER INTERNATIONAL INC., LAW DEPARTMENT ONE BAXTER PARKWAY, DF3-2E DEERFIELD, IL 60015			RAZA, SAIRA B	
		ART UNIT	PAPER NUMBER	1711
DATE MAILED: 08/08/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,758	LING ET AL.	
	Examiner	Art Unit	
	Saira Raza	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 June 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-13,15,16,18-20,22,24-26 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-13,15,16,18-20,22,24-26 and 28-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 1, 2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
- a. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 1-2, 4-13, 15-16, 18-20, 22, 24-26, and 28-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms “outermost” and “solution contact” have been recited in the claims to somehow limit the structure of the layering and type of contact between the layers, respectively.
4. Although the specification provides support for an “outer” layer, it does not appear to support an “outermost” layer. The two terms outer and outermost can be considered to describe distinct positions in the layering structure, for example the term “outer” can encompass more than one layers which are situated father out from the core layer. On the other hand, the term “outermost” is considered to describe a layer which is the farthest out from the core, and does not

have any subsequent layers which are farther out from the core layer. The relationship between the term outer and outermost is analogous to the genus and species relationship. Wherein disclosure of the genus does not provide support for all species contained thereof. Hence, disclosure of outer does not provide support for outermost.

5. In reference to the term “solution contact,” it appears that applicant’s specification does not provide support or guidance as to the requirement(s) for this type of contact.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2, 4-13, 15-16, 18-20, 22, 24-26, and 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “solution contact” renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisites, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-2, 4-13, 15-16, 18-19, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo et al. in view of Laurin et al.

10. Woo discloses a multi-layered non-PVC containing tubing structure comprising an outer layer, a tie layer, and an inner layer (abstract). The outer layer can comprise 40-99% by weight of a

polypropylene copolymer having 2-6% polyethylene and 1-60% by weight of a styrene-ethylene-butylene-styrene (SEBS) thermoplastic elastomer copolymer (col. 3 lines 10-17).

11. In reference to the newly added limitation regarding an outermost first layer, it is noted as per Figure 1 in Woo, that the outer layer is the outermost layer since the tubing structure of Woo does not have any subsequent layers which are farther out from the core layer.

12. A second layer, the tie layer, comprises 30-60% by weight of a Hytrel copolyester, 0-20% by weight of a polypropylene copolymer having 2-6% polyethylene, 30-60% by weight of a SEBS thermoplastic elastomer, and 0-30% by weight of ethylene-vinyl acetate (col. 3 lines 38-49). Note that the applicant recognizes the exemplified copolyester, Hytrel 4056, as a polyester polyether block copolymer and recognizes the exemplified ethylene-vinyl acetate, UE 697, as a suitable material having the claimed vinyl acetate content. In this sense, the second layer is coaxially mounted within the first layer.

13. In reference to the newly added limitation regarding a solution contact second layer, it is the examiner's position that the term "solution contact" is a process limitation, hence would not materially differentiate the claimed layer from the layer of the prior art.

14. Regarding claim 34, it is noted that the second layers are bonded to a second tubing (figures). It is the examiner's position that the process for bonding the tubing would not materially differentiate the claimed tubing from the tubing of the prior art (product-by-process claim). Therefore, the prior art teaches this bonded layer.

15. Regarding claim 35, Woo teaches that the tubing is attached to containers made from flowable materials; thus, the reference teaches that the first layer is attached to a flowable material container (col. 4 lines 29-40).

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16. Woo applies as above, teaching multi-layered tubing structures having blended components but failing to mention the claimed second polyolefin polymer or RF susceptible polymer of layer 1. Woo also does not disclose the claimed functionalized block copolymers. Laurin teaches similar blend compositions, where polypropylene polymers are blended with a second polyolefin, a dimer fatty acid polyamide or other RF susceptible polymer, and a compatibilizing block copolymer thermoplastic elastomer (col. 4 lines 1-23). The examples demonstrate the claimed amounts of components. SEBS copolymers are preferably functionalized with maleic anhydride or other polar monomers to enhance the compatibility with polar polymers (col. 7 lines 37-50). Thus, it would have been prima facie obvious to use maleic anhydride-modified SEBS polymers in the Woo invention to enhance the compatibility of non-polar polymers with polar polymers. The additional polyolefin serves to confer flexibility and low temperature ductility to the blend, and the RF polymer imparts RF dielectric loss. Thus, it would have been prima facie obvious to use the claimed components in the first layer of the Woo reference to improve flexibility, low temperature ductility, and RF dielectric loss.

17. Regarding the second layer, Woo applies as above, failing to teach the combination of a thermoplastic elastomer and a copolymer selected from the claimed Markush group. Laurin teaches blends of polyolefins and polar polymers, where both SEBS and functionalized SEBS materials are used as a compatibilizer for the polar and non-polar components (col. 7 lines 38-58). It is the examiner's position that it would have been prima facie obvious to include both the SEBS and functionalized SEBS components in the second layer, blended tie layer, of Woo in any amounts sufficient to optimize the compatibility of the polar and non-polar components.

18. Claims 20, 22, 24-26, 28-33, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo et al. in view of Laurin et al., and further in view of Strassmann.

19. Woo and Laurin apply as above, teaching multi-layered tubing structure for tubing ports, but failing to teach the newly added limitations regarding the outermost second layer. They also fail to teach, as per claim 22, that the first blend layer is coaxially mounted within the second blend layer. Strassmann teaches tubing port structures, where the bag is mounted coaxially onto the outside of the tubing (figures). The bags are made of the same blend materials as the outer layers of the tubing to optimize adhesion (examples). It would have been prima facie obvious to use bags of blended materials and mount the bags onto the outer layer of the tubing to provide conventional bag structures having optimized adhesion to the tubing.

20. Specifically, it would have been obvious to have the outermost layer of the tubing and the innermost layer of the bag be the taught blended tie layer (second layer), since this layer is known to contain polar and nonpolar groups which exhibit excellent bonding properties to adjacent layers. It is clear that when the outermost layer of the tubing is the blended tie layer then the first layer is coaxially mounted therein, since, as per the disclosure of Woo, the tie layer and first layer are coaxial to each other and possess strong adhesion (Woo col. 3, lines 38-51).

21. In reference to the newly added limitation regarding a solution contact first layer, it is the examiner's position that the term "solution contact" is a process limitation, hence would not materially differentiate the claimed layer from the layer of the prior art.

22. Regarding claim 36, which states that the second layer is solvent bonded to a second tubing, it is the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention to apply to the exterior of the taught tubing structure duplicate tubing. The motivation to do so would have been to further improve flexibility, low temperature ductility, and

RF dielectric loss. It has been held that duplication of parts is *prima facie* obvious. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

23. Regarding claim 37, it is the examiner's position that the claim as constructed does not require the entire outermost tubing structure to be comprised of a seamless second layer, hence there exist minor portions wherein the first layer is the outermost. Subsequently, upon adhering of the tubing port to the flexible bag, the first layer is attached to the flowable material container.

Response to Arguments

24. In response to applicant's arguments against the references individually, specifically Woo and Laurin, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

25. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine Laurin with Woo is to improve the first and second layers of Woo by including the components of Laurin. Specifically, advantages in the outer layer of Woo include improved flexibility, low temperature ductility, and RF dielectric loss, and advantages in the second tie layer of Woo include improved the compatibility of the polar and non-polar components.

26. In reference to applicant's argument that one of ordinary skill in the art would recognize that a tie layer is inherently not an outermost layer, it is noted that the port tube taught above is adhered

to a flowable container as disclosed by the references. Hence, one of ordinary skill in the art would readily recognize that employment of the tie layer as the outermost layer would provide beneficial adhesion. The outermost blended tie layer of the port tube is contacted with the flowable container at the innermost identical blended tie layer, in essence, the combination of the two identical tie layer's are bonding the first layer of the port tube and the layer of the flowable container which is adjacent to the innermost tie layer. Hence one of ordinary skill in the art would recognize this benefit and employ the tie layer as the outermost layer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Raza whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James J. Seidleck
Supervisory Patent Examiner
Technology Center 1700